HERMES DECLARATION
EXHIBIT 16

An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture

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• An ultrastrong polyethylene fiber was evaluated as an ophthalmic suture. Properties of this fiber and of nylon, polypropylene, and polyester sutures were measured by standard techniques for fiber testing and for testing knot characteristics of sutures. Their behavior in cataract and keratoplasty surgery was assessed qualitatively. The ultrastrong polyethylene fiber has great tensile strength, high flexibility, and is very inelastic. Its strength and knot security provide safe incision closure and it has good biocompatibility. Ultrastrong polyethylene fiber is potentially superior to nylon, polypropylene, and polyester in the most important characteristics of a nonabsorbable monofilament polymer ophthalmic microsuture.

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In the 1960s, when the surgical microscope dramatically transformed surgery of the anterior segment of the eye, the most advanced suture material was the 40-μm (8-0) twisted multifilament virgin silk of Barraquer. Silk has excellent handling and knotting characteristics because it is very flexible and inelastic, and it has a highly textured surface. Surgeons using it as a microsuture were dissatisfied with it, however, because they believed that its strength was not adequate and they considered it too large for microsurgery. Also, since silk is of biologic origin, it causes significant tissue reaction; this and its biodegradability further limit its effectiveness in maintaining security of incision closure.

Microscopic eye surgery required a better suture material. In the early 1960s, the synthetic polymer, nylon, led to a further transformation in eye surgery. Undyed 40-μm nylon monofilaments were first used in eye surgery at the University of Tubingen in Germany.[1] Subsequently, 25-μm black-dyed nylon was provided by manufacturers, and for most eye surgeons it soon replaced silk because it was so much finer, stronger, and more inert. Although handling and knotting nylon sutures is more difficult because they are less flexible, more elastic, and smoother than silk, surgeons soon adapted to these characteristics. Two polymer monofilament sutures for eye microsurgery subsequently appeared that are comparable to nylon in their strength, flexibility, elasticity, and biocompatibility—polypropylene in the 1970s and polyester in 1983—but nylon continues today to be by far the most commonly used suture for anterior segment surgery.

Sutures of a fourth polymer, polyethylene, have also been available, but they have not been used for eye surgery. Histologic studies of polyethylene sutures have shown that they produce minimal tissue reaction, comparable to that of nylon, polypropylene, and polyester.[2,3] Polyethylene is widely used in orthopedic surgery as a replacement material for artificial hip-joint and knee components because of its excellent mechanical properties, biocompatibility, and biostability.[4-7]

Recently, ultrastrong polyethylene fibers have been produced with new methods of polymer processing.[8] These fibers have a tensile strength of up to 4.7 times greater than that of comparable steel wire, and they are also very inelastic and very flexible.

In this study, we evaluated ultrastrong polyethylene fibers in comparison with nylon, polypropylene, and polyester ophthalmic sutures by (1) measurement of mechanical properties with standard fiber-testing techniques, and (2) qualitative assessment of their behavior as sutures during their use in catarart and keratoplasty surgery, and of the appearance on postoperative examinations of the tissue response and of the fiber itself.

MATERIALS AND METHODS

The ultrastrong polyethylene fibers used in this study were made from an ultrahigh-molecular weight source material, Hi-Fax 1900 linear polyethylene, having a weight-average molecular weight of about 4×10^6 kg/kmole. The fibers were produced by hot-drawing of filaments obtained by a process of crystallization from flowing solutions of the polymer ("surface growth" technique). Details of these processes are described elsewhere.[8,9]

The polyethylene fibers are monofilaments with a ribbon shape. The nylon, polypropylene, and polyester ophthalmic sutures evaluated are round monofilaments; they were taken from commercially purchased packages of 10-0 sutures for

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operating room use of black Ethilon, blue Prolene, and green Mersilene, respectively (Ethicon Inc).

Mechanical Testing

Suture sizes are given designations based on their diameters, on the assumption they are round; those with a diameter of from 20 to 29 μm are designated as 10-0 according to the *US Pharmacopoeia*.[4] The cross-sectional area of each of the four fibers has to be taken into account in comparing the results of mechanical properties testing. The cross-sectional area was determined under exclusion of pores by dividing the mass per unit length by the density of the material, assuming for polyethylene, 1,000 kg/cu m; for nylon 6/6, 1,130 kg/cu m; for isotactic polypropylene, 900 kg/cu m; and for polyester (polyethylene terephthalate), 1,457 kg/cu m. To show the shape and structure of the polyethylene fibers, specimens were gold coated and then examined in a scanning electron microscope, operated at 20 to 40 kV.

The standard method for determining the mechanical properties of a suture is by measuring its response to an applied load according to the procedure specified by the *US Pharmacopoeia*.[4] Each end of the fiber is held by a clamp in a tensile strength testing machine. One clamp is connected to a motor-driven screw that loads the fiber by separating the clamps at a constant speed, and the other clamp is attached to a force gauge. The response of a fiber (at each point during the loading) is expressed as *stress*, which is the measured force divided by the cross-sectional area, and *strain*, which is the measured elongation. The appropriate unit of stress for monofilaments[4] is the gigapascal (GPa), which is equivalent to 1,000 newton/sq mm; strain is reported as percentage increase in length of the specimen. The result of this testing is a "stress-strain curve" and the tensile strength of a fiber is the stress at the end of the curve, the point at which the fiber breaks. From the stress-strain curve of a material is derived the modulus of elasticity (Young's modulus, E), a constant in the equation relating stress to strain.

The mechanical properties of the fibers in this study were measured dry and at room temperature using a tensile strength tester with pneumatic clamps (Instron, models 1195 and 2712-002). The distance between the clamps and the clamp separation speed was 10 to 12 mm/min. The values presented are the average of five tests; measurement error is about 0.02 GPa. The configuration of knots tested in this study is described by a code[4] in which the number of turns for each throw is indicated in numerals and the manner of joining the throws is shown by = for in parallel (square) and × for crosswise (granny).

The basic stress-strain curves for fibers of each of the four materials tested were obtained with a continuous, unknotted specimen loaded in the axial direction of the fiber; *tensile strength* is the end point, the point at which the fiber breaks.

A second series of stress-strain curves was obtained by loading the ends of a single, continuous fiber that is tied with a surgical knot (2 = 1) around flexible rubber tubing of 6.5-mm inside diameter and 1.6-mm wall thickness.[4] These curves show the weakening effect of a knot on each fiber; the *knot pull strength* is the end point, the point at which fibers knotted in this way break.[4]

A third series of stress-strain curves was obtained by loading a specimen of two segments of a fiber joined by a knot. It is prepared from a single continuous fiber by first tying a knot of the configuration to be tested around a tube and then cutting the loop thus formed, yielding a specimen of two strands joined by the knot. These stress-strain curves give an indication of the security of that particular knot configuration with that fiber; *knot holding strength* is the end point, the point at which the knot breaks or slippage through the knot is observed.

Although there are no standard methods to describe quantitatively the important property of suture flexibility, it is related to torsional stiffness which can therefore be used as an approximate measure of flexibility.[4] Fibers of the four materials equal in length (0.245 m) were held vertically and loaded with a weight (0.5×10^{-3} kg) attached at one end. The upper end of the fiber was rotated until the weight also started to rotate. The number of turns a fiber takes before the weight starts to rotate constitutes a relative measure of its flexibility. Because silk has always been highly valued for its excellent flexibility, it was also tested in this way. Because the finest-diameter silk suture commercially available is 9-0 black twisted virgin silk (Ethicon), specimens of it were compared with polyethylene fiber of about the same cross-sectional area.

Clinical Evaluation

The performance of the ultrastrong polyethylene fiber as an ophthalmic suture was evaluated qualitatively by observing its behavior during surgery. Its biocompatibility and functional adequacy after surgery were assessed, also in a qualitative way, on postoperative examinations. These observations were compared with prior experience in cataract surgery with the nylon in several thousand operations and the polypropylene in several hundred operations, and with subsequent experience with the polyester in several hundred operations. The comparisons in the keratoplasties were with several dozen in which the nylon was used.

Between February 1982 and April 1984, the polyethylene fiber was used to close 237 corneoscleral cataract incisions and, in nine patients, for penetrating keratoplasty. In the cataract operations it has also been used for suturing iris and conjunctiva. Lengths of the undyed ribbon-shaped polyethylene fiber having a width of 37 μm and a thickness of 15 to 25 μm were threaded and tied to an eyed "flat-lancet point" needle; this needle has a wire size of 150 μm, a 4-mm chord length, and a ⅜ curve; its eye is 60 × 250 μm. For corneoscleral incision closure, after placing a central apposition suture, a continuous chain[4] (running interlocking[4]) suture was used. A single continuous running suture was used in the keratoplasties. All knots were of the 3 = 2 = 1 "reinforced" configuration.[4]

During Surgery.—The response of the polyethylene fiber to the three basic suture-related surgical maneuvers (placement, tightening, and knot tying) was assessed during surgery on the basis of the usual visual and kinesthetic observations. Among the mechanical properties evaluated that affect a suture's handling characteristics are tensile strength, shear strength, compressive strength, elasticity, flexibility, and surface friction. Tensile, shear, and compressive strength affect a suture's behavior during pulling, bending, and grasping, respectively; elasticity, flexibility, and friction are factors in suture response to stretching, bending, and tissue drag, respectively.

During suture placement, as it is pulled through the needle track, the suture is subject primarily to tensile stress, acting along the direction of pull. Shear stress occurs near the point of attachment of suture to needle, whether it is swaged or threaded through an eyed needle. Resistance to pull-through affects the amount of tensile and shear stress in the suture. Surface friction and flexibility of a suture material are factors in the pull-through resistance of the suture as it enters, follows, and exits the suture canal.[2]

During suture tightening, in addition to visual cues of tissue stress, proper apposition pressure is achieved by sensing the reaction force in the suture. Elasticity contributes to the suture tension, and this affects the kinesthetic estimation of incision closure pressure. In addition to tensile and shear stress in the suture, during tightening there is also the compressive stress from the forceps grasp.

The behavior of the fiber during knot tying was also observed and is also determined by several mechanical properties. Tensile, shear, and compressive strengths are necessary to maintain the integrity of the knot as it is tied. Flexibility and surface friction determine the amount of force required for knot tying and also the tendency of the knot to slip and become too tight.

Postoperatively.—The tissue response to the polyethylene suture and the appearance of the suture itself were assessed on routine postoperative evaluations beginning on the first day after surgery. Irritative symptoms were evaluated and then slit-lamp examination was performed.

In the cataract cases, the early postoperative reaction is obviously due primarily to the conjunctival dissection and the presence of the conjunctival suture, and the conjunctival flap often limits the visibility of the corneoscleral suture. With removal of the conjunctival suture, the conjunctival reaction subsides in a relatively predictable way unless the response to the corneoscleral suture prolongs it. As visualization of the corneo-scleral suture improves, any possible isolated response of the

through the eye of the needle. In only two instances did it break at this point of extreme bending despite the multiple passes through the tissue. Sutures of the other three polymers used with an eyed needle characteristically resist this bending for only a few passes before breaking. While using the polyethylene fiber, full confidence developed that the possibility of fiber break was not a factor during surgery. When this series was completed and subsequent surgery was performed using the other polymer sutures, the amount of stress that they could sustain without break had to be "relearned."

An important property of the polyethylene fiber which is apparent during surgery is that it is very inelastic. This makes proper tension on the fiber easier to obtain during tightening a continuous suture and the first throw of a knot because of the negligible contribution of fiber stretch to the kinesthetic estimation of apposition pressure. The polyethylene fiber conducts mechanical tension so well that one obtains a direct sense of the tissue stress during tightening and tying.

Another attribute of the polyethylene fiber observed during its use as a suture is its flexibility. It tends to behave much like silk and without the kinks or corkscrew formations typical of the other polymers and thus handles more easily. It readily conforms to the tissue surface because it does not have a wiry springiness. The behavior of the polyethylene fiber at the eye of the needle illustrates its high flexibility: it can be tied to the needle with adequate security with a single throw. All three polymer sutures characteristically require a more complex knot because of the "unlooping" tension caused by their relative inflexibility.

The polyethylene fiber appears to have relatively low surface friction, and this agrees with measurements in a previous study that included polyethylene sutures.[3] Although the polyethylene fiber has a flat cross section, high flexibility, and relatively low friction, no difference from the other suture materials in pull-through resistance (tissue drag) could be detected in its passage through corneo-scleral or corneal tissue.

A definite limitation of the polyethylene fiber during its use in surgery was that it was undyed. For this reason it was used in 37-μm-wide ribbons that appear larger than 10-0 round monofilaments. Undyed 25-μm-wide polyethylene fibers were too fine for adequate visualization.

Finally, because of the polyethylene fiber's flat shape, its low friction, and its softness (with forceps compression it can become even flatter), handling the fiber requires tying forceps with jaws that properly appose in order to get enough traction for adequate tightening and tying tension. The characteristics that affect its tightening and tying, and its remarkable strength and flexibility, affect the cutting of it, and so sharp scissors with properly adjusted blades are necessary. Holding tension on the fiber makes it easier to cut because this prevents it from sliding between the scissors blades. Scissors used for cutting the polyethylene fiber tend to become dull sooner than when they are used for cutting the other polymer sutures.

Postoperatively.—Beginning the day after cataract surgery, from patients' descriptions of irritative symptoms and from slit-lamp evaluation of the response of conjunctiva, corneoscleral tissue, and iris, when it was sutured, no difference was distinguished in the biocompatibility of the polyethylene fiber when compared with the experience with the series of cataract operations in which the three commercially available polymer sutures were used. The polyethylene fiber provided good closure of the corneoscleral incision and resulted in the typical amount of early with-the-rule astigmatism that usually receded spontaneously to the desired level of less than 2 diopters. Occasionally, one or more of the limbs of the corneoscleral suture were cut with a blade fragment to relieve tension and reduce astigmatism, just as is done with sutures of the other polymers.

With the use of polyethylene fiber, rare instances were observed of spontaneous untying of the knot of the apposition suture or the beginning knot of the continuous corneoscleral suture, just as in the other series with the polymer sutures. But with the polyethylene fiber, the final knot of the continuous suture occasionally did spontaneously untie. The frequency of this phenomenon cannot be determined because of the variable visibility of corneoscleral sutures, especially of this undyed one. Untying of this knot was observed infrequently with the other, more visible, dyed polymer sutures: it is certainly more common with the polyethylene. When it was observed, this was generally a month or more after surgery. The explanation for this untying lies in the termination of a continuous chain suture: the knot is tied from the free end and a bight (a loop) drawn from the last limb,[22] resulting in a knot tied with three strands of the fiber instead of the usual two. Because of the high flexibility and low friction of the polyethylene fiber, two of the strands act like tracks, permitting the third to slip. In these instances, and throughout the entire series of cataract incisions closed with the polyethylene fiber, against-the-rule astigmatism that would occur with wound stretching was no more frequent than in the series in which sutures of the other three polymers were used.

A second occasional postoperative observation of both the continuous corneoscleral and keratoplasty sutures was the unravelling and exposure of exceedingly fine microfilaments from the edge of the fiber, usually within two months of surgery. This caused minor irritative symptoms that were eliminated by stripping the microfilament with a jeweler's forceps or cutting it with scissors; this had no effect on the security of the incision closure. Breakage of the fiber was never observed postoperatively.

After keratoplasty using the polyethylene fiber, from the first postoperative day, patients' complaints of irritation were much less than when this operation is performed using the other polymer sutures. Improved patient comfort continued even if an end of the single knot became exposed and also even when one or more limbs remained above the epithelial surface. This is due to its flat shape with a thickness of only several micrometers, its high flexibility, and its low friction. With the polyethylene fiber, knots are small and compact, and limbs readily conform to the shape of the corneal surface, lying flat up to each point of entry and exit. Suture-stimulated vessel ingrowth into the graft has not been observed, even where a knot or limb is exposed. Graft-host edge apposition is better controlled in the polyethylene fiber-sutured grafts, as indicated by fewer focal peripheral graft striae. This may be attributed to the fact that the fiber is very inelastic, which permits more precise estimation of suture tension during tightening.

COMMENT

There is good agreement between the results of the laboratory testing of the mechanical properties of the ultrastrong polyethylene fiber and the observations made during and after surgery. The polyethylene fiber has remarkably high tensile strength and

flexibility. Suture break as a factor during both cataract and keratoplasty surgery with this fiber is actually eliminated in all the manipulations a continuous suture is subjected to—a most unusual attribute in an ophthalmic suture. Further, it is very inelastic in comparison with the other suture materials, and this permits especially sensitive control during suture tightening and tying. This characteristic is especially advantageous in keratoplasty because the graft position is critically dependent on the suture. In both the laboratory testing and in use during surgery, the polyethylene fiber showed great flexibility, a valuable attribute that gives it what surgeons of the premicrosurgery era would describe as "hand" superior even to the standard of that period—silk.

The knot pull strength of the polyethylene fiber is also high, which indicates the potential for superiority over conventional polymer sutures in the important aspect of knot security. Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull strength. Considering the surprising security of this fiber when tied to an eyed needle with only a single throw, the conventional knot testing procedures may not provide a full characterization of the complex aspect of knot security.

Postoperatively, in cataract incision closure the polyethylene fiber showed the same biocompatibility characteristics as the sutures currently being used. The one situation in which knot security with the polyethylene is different from the other sutures was the occasional observation of knot slippage where three strands of the fiber are included in the knot of a continuous cataract incision closure suture, but this did not affect the security of incision closure.

Postoperatively, in keratoplasty the polyethylene fiber seems superior in every way to the commercially available sutures. Considering biocompatibility to include the effects on ocular tissue of its flat shape, high flexibility, and low surface friction, this fiber is superior as a suture for keratoplasty.

A minor inconvenience is the occasional unravelling of microfilaments from the fiber, sometimes causing irritation until they are removed. And obviously, this fiber is more difficult to work with because it is undyed. Whether the polyethylene fiber will biodegrade over time cannot be determined at this time because of the limited period of follow-up; no evidence of it has been observed to the present.

Further refinements in the process of preparation of the ultrastrong polyethylene fiber may lead to its acceptance as an ophthalmic microsuture. First, it will be much easier to see during surgery because it has been successfully dyed so that 25-μm-wide ribbons of it are as visible as 10-0 polypropylene (unpublished results). Second, the use of a "gel-spinning" process should yield a fiber with a more compact filament structure and thus eliminate the occasional unravelling of microfilaments.[4,21] Finally, to increase the polyethylene fiber's surface friction, its surface texture might be improved by surface structurization.[20]

The authors do not have any commercial or proprietary interest in the ultrastrong polyethylene fiber discussed in this article and had no financial interest as evaluators of the ultrastrong polyethylene fiber.

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References

1. Harms H, Mackensen G: *Ocular Surgery Under the Microscope*. Chicago, Year Book Medical Publishers Inc, 1967.

2. Gomel V, McComb P, Buer-Meisel M: Histologic reactions to polylactin-910, polyethylene and nylon microsuture. *J Reprod Med* 1980;25:56-59.

3. Sulthouse TN, Matlaga BF: Significance of cellular enzyme activity at nonabsorbable suture implant sites: Silk, polyester, and polypropylene. *J Surg Res* 1975;19:127-132.

4. Pennisi VR, Shapiro RL, Boucher JH, et al: Marlex 50 as a replacement for the mandibular condyle. *Plast Reconstr Surg* 1965;35:212-217.

5. Sauer BW, Weinstein AM, Klawitter JJ, et al: The role of porous polymeric materials in prosthesis attachment. *J Biomed Mater Res* 1974;5:145-153.

6. Cestero HJ, Salyer KE, Toronto IR: Bone growth into porous carbon, polyethylene, and polypropylene prostheses. *J Biomed Mater Res* 1975;6:1-7.

7. Grugnola AM: Ultra-high molecular weight polyethylene as used in articular prosthesis (a molecular weight distribution study). *J Appl Polymer Sci* 1976;20:809-812.

8. Pennings AJ, Smook J, de Boer J, et al: Process of preparation and properties of ultra-high strength polyethylene fibers. *Pure Appl Chem* 1983;55:777-798.

9. Torfs JCM: *Ultra-strong Polyethylene Fibers Produced by Crystallization From Flowing Solutions*. thesis. Groningen, the Netherlands, 1982.

10. Torfs JCM, Smook J, Pennings AJ: Ultra-strong polyethylene fibers produced by crystallization from flowing solutions. *J Appl Polymer Sci* 1983;28:57-75.

11. Kalb B, Pennings AJ: Maximum strength and drawing mechanism of hot-drawn high molecular weight polyethylene. *J Mater Sci* 1980;15:2584-2590.

12. Smook J, Torfs JCM, van Hutten PF, et al: Ultra-high strength polyethylene by hot-drawing of surface growth fibers. *Polymer Bull* 1980;2:291-300.

13. Smook J, Torfs JCM, Pennings AJ: Hot drawing of surface growth polyethylene fibers: 2a. Effect of drawing temperature and elongational viscosity. *Makromolekulare Chemie* 1981;182:3351-3359.

14. *Pharmacopoeia of the United States*. Easton, Pa, Mack Publishing Co, 1980, vol 20, pp 759, 983-984.

15. Chu CC: Mechanical properties of suture materials: An important characterization. *Ann Surg* 1981;193:365-370.

16. Tera H, Aberg C: Tensile strengths of 12 types of knots employed in surgery, using different suture materials. *Acta Chir Scand* 1976;142:1-7.

17. Holmlund D: Knot properties of surgical suture materials: A model study. *Acta Chir Scand* 1974;140:355-362.

18. Holmlund D, Tera H, Wiberg Y, et al: *Sutures and Techniques for Wound Closure*. New York, Medical and Surgical Publications, Naimark & Barba Inc, 1975.

19. Elsner G: *Eye Surgery: An Introduction to Operative Technique*. New York, Springer-Verlag, 1980.

20. Ryan SJ, Maumenee AE: The running interlocking suture for cataract surgery. *Am J Ophthalmol* 1971;85:302-303.

21. Hermann JR: Tensile strength and knot security of surgical suture materials. *Am Surg* 1971;37:209-217.

22. Flinn RM: Knotting in medicine and surgery. *Practitioner* 1969;183:322-328.

23. Smook J, Pennings AJ: Elastic flow instabilities and shish-kebab formation during gel-spinning of ultra-high molecular weight polyethylene. *J Mater Sci* 1984;19:31-43.

24. Smith P, Pennings AJ: Surface structurization of isotactic polypropylene filaments by quenching in liquids. *Polymer Lett Ed* 1976;14:29-34.

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EXHIBIT 17

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(12) **United States Patent**
Grafton et al.

(10) **Patent No.: US 6,716,234 B2**
(45) **Date of Patent: Apr. 6, 2004**

(54) **HIGH STRENGTH SUTURE MATERIAL**

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(73) Assignee: **Arthrex, Inc.**, Naples, FL (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 5 days.

(21) Appl. No.: **09/950,598**

(22) Filed: **Sep. 13, 2001**

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(51) **Int. Cl.**[7] **A61L 17/04**
(52) **U.S. Cl.** **606/228**
(58) **Field of Search** 606/228

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,942,532 A		3/1976	Hunter et al.	
4,047,533 A	*	9/1977	Perciaccante et al.	606/230
4,344,908 A		8/1982	Smith et al.	264/203
4,411,854 A		10/1983	Maurer et al.	264/205
4,422,993 A		12/1983	Smith et al.	264/210.8
4,430,383 A		2/1984	Smith et al.	428/364
4,436,689 A		3/1984	Smith et al.	264/204
4,668,717 A		5/1987	Lemstra et al.	523/322
5,019,093 A	*	5/1991	Kaplan et al.	606/228
5,067,538 A		11/1991	Nelson et al.	152/451
5,234,764 A		8/1993	Nelson et al.	428/364
5,261,886 A	*	11/1993	Chesterfield et al.	606/228
5,318,575 A		6/1994	Chesterfield et al.	606/151
5,383,925 A	*	1/1995	Schmitt	623/1.53
5,403,659 A		4/1995	Nelson et al.	428/364
5,540,703 A		7/1996	Barker, Jr. et al.	
5,630,976 A		5/1997	Nelson et al.	264/210.8
5,720,765 A	*	2/1998	Thal	606/232
6,045,571 A	*	4/2000	Hill et al.	606/228
6,063,105 A	*	5/2000	Totakura	606/228

FOREIGN PATENT DOCUMENTS

EP 0561108 A2 9/1993

OTHER PUBLICATIONS

"SecureStrand™ Cable System," Surgical Dynamics, Inc. 1999.

* cited by examiner

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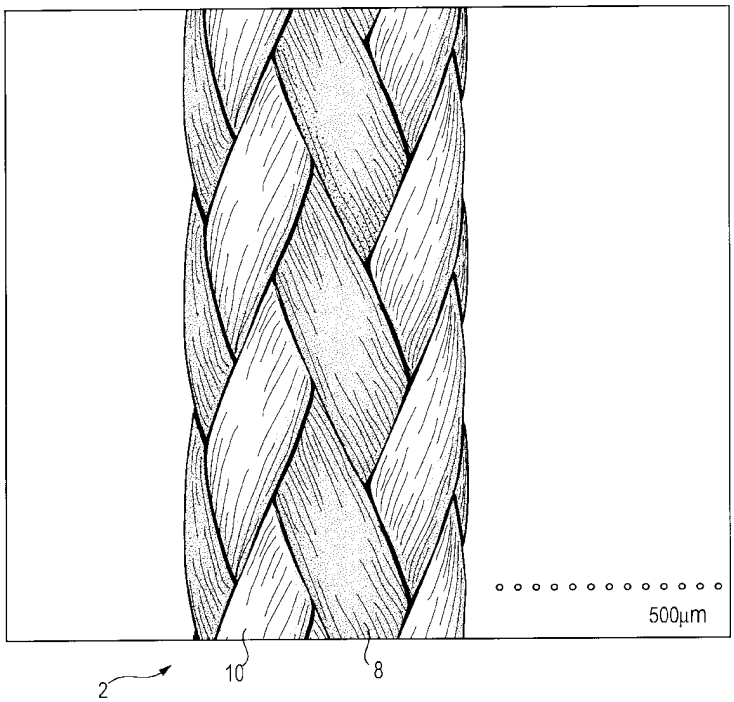
(57) **ABSTRACT**

A high strength abrasion resistant surgical suture material with improved tie down characteristics. The suture features a multifilament cover formed of braided strands of ultra high molecular weight long chain polyethylene and polyester. The cover surrounds a core formed of twisted strands of ultrahigh molecular weight polyethylene. The suture, provided in a #2 size, has the strength of #5 Ethibond, is ideally suited for most orthopedic procedures, and can be attached to a suture anchor or a curved needle.

9 Claims, 2 Drawing Sheets



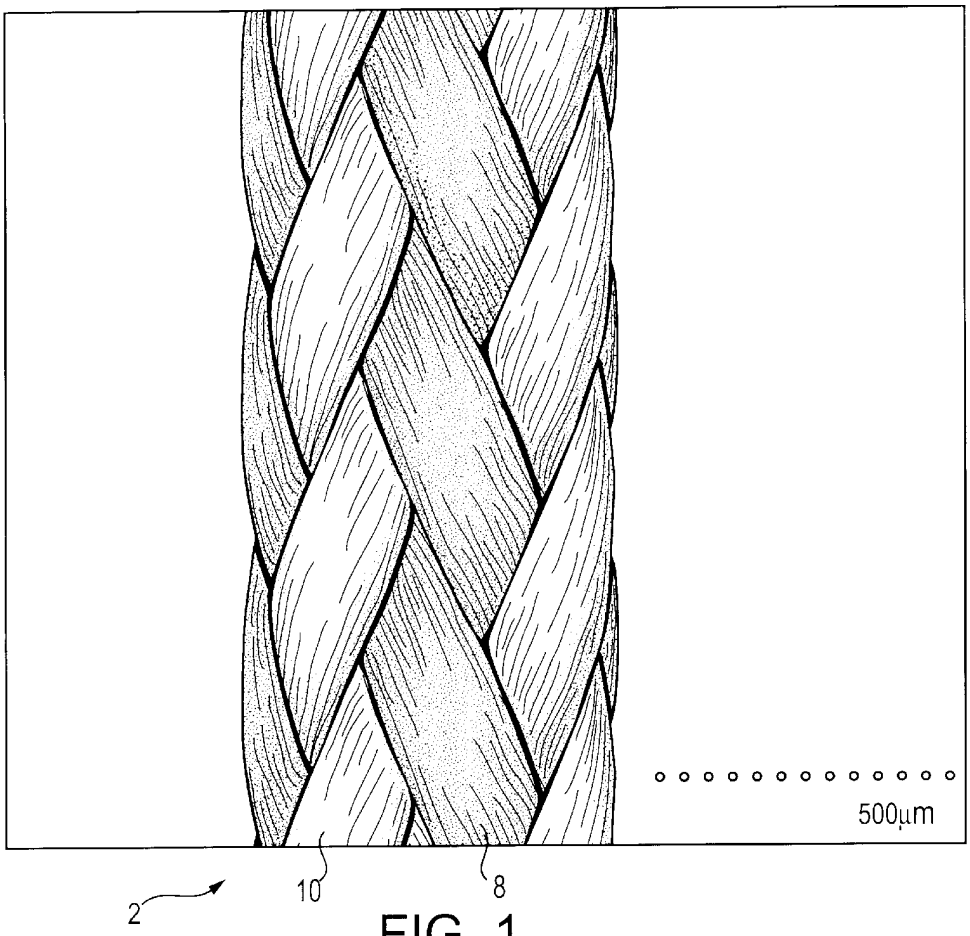


FIG. 1

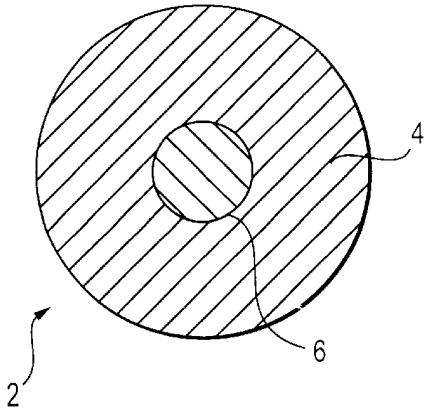


FIG. 2

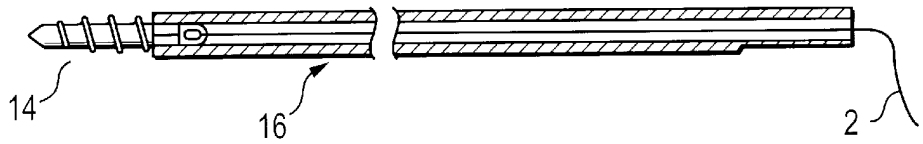


FIG. 3

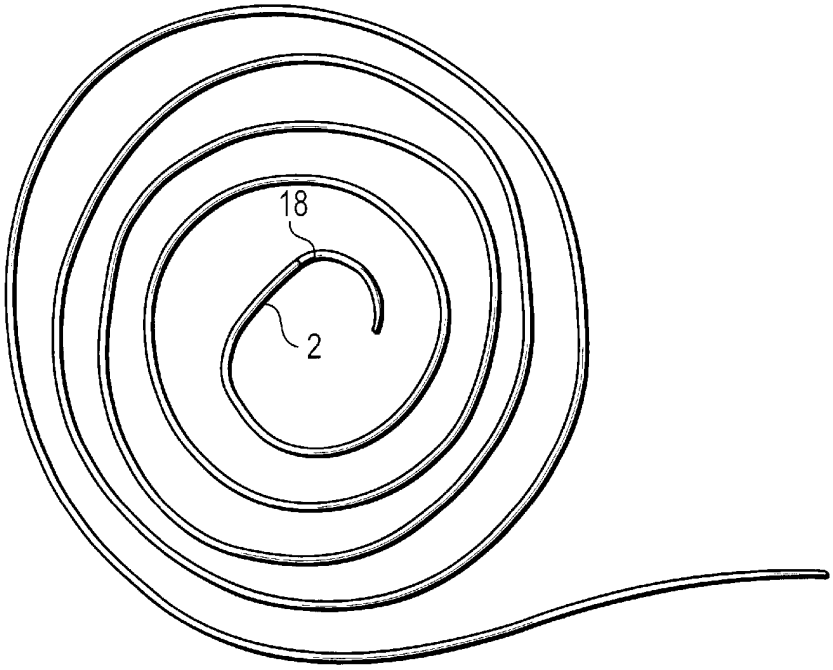


FIG. 4A

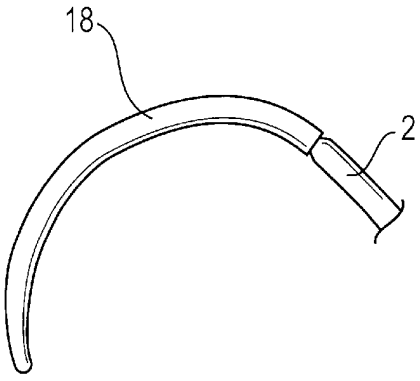


FIG. 4B

HIGH STRENGTH SUTURE MATERIAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to high strength surgical suture materials, and more particularly to braided suture blends of ultrahigh molecular weight polyethylene and polyester having high strength and excellent tie down characteristics.

2. Description of the Related Art

Suture strength is an important consideration in any surgical suture material. One of the strongest materials currently formed into elongated strands is an ultrahigh molecular long chain weight polyethylene, typically used for fishing line and the like, which is sold under the trade names Dyneema or Spectra. However, this material, while much stronger than ordinary surgical suture, does not have acceptable knot tie down characteristics for use in surgical applications.

SUMMARY OF THE INVENTION

The present invention advantageously provides a high strength surgical suture material with improved tie down characteristics. The suture features a braided cover made of a blend of ultrahigh molecular weight long chain polyethylene and polyester. The polyethylene provides strength. The polyester provides improved tie down properties.

The preferred suture includes a multifilament cover formed of a plurality of fibers of ultrahigh molecular weight polyethylene braided with fibers of polyester. The cover surrounds a core of twisted fibers of ultrahigh molecular weight polyethylene.

Preferably, the ultrahigh molecular weight polyethylene includes about 60% of the cover fibers, with polyester making up about 40% of the cover filaments. The core comprises about 30% of the suture, the cover making up about 70%. As an enhancement, the suture is provided with a coating on the cover, as is known in the prior art. The suture can be packaged ready for use attached to a suture anchor.

Ultrahigh molecular weight polyethylene fibers suitable for use in the present invention are marketed under the Dyneema trademark by Toyo Boseki Kabushiki Kaisha.

The suture of the present invention advantageously has the strength of Ethibond #5 suture, yet has the diameter, feel and tie ability of #2 suture. As a result, the suture of the present invention is ideal for most orthopedic procedures such as rotator cuff repair, archilles tendon repair, patellar tendon repair, ACL/PCL reconstruction, hip and shoulder reconstruction procedures, and replacement for suture in anchors.

Other features and advantages of the present invention will become apparent from the following description of the invention which refers to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWING(S)

FIG. **1** is a copy of a scanning electron micrograph of a length of suture according to the present invention.

FIG. **2** is a schematic cross section of a length of suture according to the present invention.

FIG. **3** is an illustration of the suture of the present invention attached to a suture anchor.

FIGS. **4**A and **4**B show the suture of the present invention attached to a half round, tapered needle.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, a scanning electron micrograph of a length of suture **2** according to the present invention is shown. Suture **2** is made up of a cover **4** and a core **6** surrounded by the cover. See FIG. **2**. Strands of ultrahigh molecular weight polyethylene (UHMWPE) **8**, sold under the tradename Dyneema or Spectra, and strands of polyester **10** are braided together to form the cover **4**. The core is formed of twisted UHMWPE.

Details of the present invention will be described further below in connection with the following examples:

EXAMPLE 1

USP Size 5 (EP size 7)

Made on a 16 carrier Hobourns machine, the yarns used in the braided cover are polyester type 712 and Dyneema SK65. The cover is formed using eight carriers with one end of 190 d'tex polyester per carrier, and eight carriers with one end of 220 d'tex Dyneema per carrier. The core is formed of Dyneema using one end of 440/1/3 twisted 10 tpi "z" and 7 tpi "s" (core is not steam set). Picks per inch (PPI)=36. In forming the suture, the percent cover is 71.31, while the percent of the core is 28.69. Runnage is 1991 meters per kilo.

Of the overall suture, the polyester in the cover (8 carriers×190 d'tex=1520 d'tex) makes up 33.04% of the suture, and the Dyneema in the cover (8 carriers×220 d'tex=1760 dtex) makes up 38.76% of the suture. The Dyneema core (3 carriers×440 d'tex=1320 d'tex) is 28.69% of the suture.

EXAMPLE 2

USP Size 2

The suture is 38.09% polyester, 61.91% UHMWPE, or about 40% polyester and about 60% UHMWPE.

The examples above are for size 2 and size 5 sutures. In the making of various sizes of the inventive suture, different decitex values and different PPI settings can be used to achieve the required size and strength needed. In addition, smaller sizes may require manufacture on 12 carrier machines, for example. The very smallest sizes are made without a core. Overall, the suture may range from 5% to 90% ultrahigh molecular weight polymer (Dyneema), with the balance formed of polyester.

The suture is preferably coated with a silicon based coating to fill in voids and provide optimum run down.

The Dyneema component of the present invention provides strength, and the polyester component is provided to improve tie ability and tie down characteristics. However, it has been found that the Dyneema provides an unexpected advantage of acting as a cushion for the polyester fibers, which are relatively hard and tend to damage each other. The Dyneema prevents breakage by reducing damage to the polyester when the suture is subjected to stress.

According to an alternative embodiment of the present invention, a partially bioabsorbable suture is provided by blending a high strength material, such as UHMWPE fibers, with a bioabsorbable material, such as PLLA or one of the other polylactides, for example. Accordingly, a suture made with about 10% Dyneema blended with absorbable fibers would provide greater strength than existing bioabsorbable suture with less stretch. Over time, 90% or more of the suture would absorb, leaving only a very small remnant of the knot.

In one method of using the suture of the present invention, the suture **2** is attached to a suture anchor **14** as shown in FIG. **3** (prepackaged sterile with an inserter **16**), or is attached to a half round, tapered needle **18** as shown in FIGS. **4**A and **4**B.

Although the present invention has been described in relation to particular embodiments thereof, many other variations and modifications and other uses will become apparent to those skilled in the art. It is preferred, therefore, that the present invention be limited not by the specific disclosure herein, but only by the appended claims.

What is claimed is:

1. A suture filament suitable for use as a suture or ligature comprising:

a cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and polyester; and

a core of twisted ultrahigh molecular weight polyethylene surrounded by the cover.

2. The suture filament of claim **1**, wherein the ultrahigh molecular weight polyethylene comprises about 60% of the braided fibers.

3. The suture filament of claim **1**, wherein the polyester comprises about 40% of the braided fibers.

4. The suture filament of claim **1**, wherein the core comprises a bout 30% of the filament.

5. The suture filament of claim **1**, wherein the cover comprises about 70% of the filament.

6. The suture filament of claim **1**, further comprising a coating disposed on the cover.

7. The suture filament of claim **1**, wherein the polyester is non-absorbable.

8. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a suture anchor attached to the suture.

9. A suture assembly comprising:

a suture having a multifilament cover formed of a plurality of braided fibers of ultrahigh molecular weight polyethylene and fibers of polyester;

a core formed of twisted fibers of ultrahigh molecular weight polyethylene; and

a half round, tapered needle attached to the suture.

* * * * *

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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Q. Okay. Do you understand this is the prosecution history of a -- of an Arthrex patent, right?
A. Yes, that's what it says.
Q. Okay. If you would turn to DMI 41091.
A. 41091, yes.
Q. Okay. At the top paragraph, do you see it says, "The suture of Example 7 of Chesterfield, et al., '575, uses a Spectra 1000 core surrounded by a hollow sheath --" I'm sorry, "a hollow braided sheath made of a single type of yarn"?
Do you see that?
A. No, where are you, starting in the middle?
Q. Right here. Right here, first paragraph.
A. First paragraph.
Q. This says --
A. Suture Example 7, is that what you're reading from?
Q. Yes, the suture --
A. Okay.
Q. Do you see that?
A. Yes, I see it.
Q. It says, "The suture of Example 7 of Chesterfield, et al., '575, uses a Spectra 1000 core surrounded by a hollow braided sheath made of

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a single type of yarn."
Do you see that?
A. Um-hum.
Q. Do you agree with that statement?
A. Yeah.
Q. Okay. And then if you go down later in the third paragraph --
A. Third paragraph, yeah.
Q. -- it says, the second sentence says, "As noted above, Chesterfield, et al., '575, does not disclose an example of a braided sheath that includes a blend of both -- of both ultra high molecular weight polyethylene and polyester."
Do you see that?
A. Yes.
Q. Do you agree with that statement?
A. Yes.
Q. Okay. When you were referring to the claims of the '575 patent -- I'd like to turn to those now.
A. Are you done with this or --
Q. Yes.
A. Number 4, the '575.
Q. It claims that it's a method for repairing split portions of body tissue. Do you see that?

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A. Yes.
Q. It goes on, it says, "comprising looping a flexible elongated member about the body tissue."
Do you see that?
A. Um-hum.
Q. Okay. What significance do you give to the meaning of going "about" the body tissue? What does that mean?
A. It --
MR. TAMBURO: Objection, vague.
THE WITNESS: "About the body tissue" is kind of funny language. Through the tissue, that's what it normally will do to produce --
BY MR. BONELLA:
Q. You mean going through the tissue?
A. That's what I would think.
Q. Okay.
A. Whether soft or hard, doesn't matter.
Q. Do you think the -- where the claim says "looping a flexible elongated member about the body tissue," do you think that FiberWire is used in going about body tissue as that's used in the claim?
A. You're asking about FiberWire?
Q. Yes.

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MR. TAMBURO: Objection, vague, and he's not an expert on how FiberWire is used in surgery.
THE WITNESS: Again, I may not know what's in surgery, but I have myself used in meniscal repair with a surgeon through the body tissue.
BY MR. BONELLA:
Q. Okay. So, is FiberWire -- to the extent you know, if FiberWire is used in surgery, is it used to go about body tissue?
A. To attach something, yes.
Q. It is? Okay. Would that be a pretty standard understanding?
A. I don't know what is standard. It's new suture, so nobody might not know that it's available. It cannot be standard.
Q. Well, no, not the FiberWire. Are sutures --
A. You asked me for FiberWire first, then you changed --
Q. The use of FiberWire, not the construction, how it's used.
A. Yeah.
Q. FiberWire, is it your understanding that it's normally used to go about body tissue?
MR. TAMBURO: Objection, vague, and he's

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A. Then polypropylene is twice, polyester is about twice -- I mean polyester -- polyethylene is twice, then -- ultra high molecular weight polyethylene is twice than polypropylene and twice than polyester, so they are probably significantly higher for the ultra high molecular weight polyethylene, knot pull strength.
Q. Do you know if -- does he provide the standard deviation for the knot pull strength?
A. He didn't, but just looking at the figures, I mean, I can say that, looking at 1.35 or 1.44, you have to say that.
Q. Okay. So, he did not provide standard deviation in this chart.
A. Not in this chart.
Q. Now, for the knot configuration four equals one equals one, do you see that?
A. Yes.
Q. The polyethylene failed at 0.35 gigapascals, which is lower than the failure value for the nylon, polypropylene and polyester for the four equals one equals one configuration, right?
A. Yes.
Q. Okay. And that's because the polyethylene slipped, right?

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A. I don't use the word "sucked."
Q. I said "slipped."
A. Slipped, okay. I thought I heard... sorry.
Q. So, the polyethylene failed at the 0.35 gigapascal level for the four equals one equals one configuration because of the polyethylene slipping, right?
A. Right.
Q. Okay. Polyethylene, including ultra high molecular weight polyethylene, is a lubricious material, right?
A. Yes.
Q. Okay.
A. It's also polypropylene -- excuse me.
Q. Sure.
A. Polypropylene is also a lubricious material.
Q. It is?
A. Yes, it is.
Q. Okay. How about nylon or polyester, are they lubricious?
A. Nylon is also -- again, is lubricious.
Q. How about polyester?
A. Polyester will be less.

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Q. And nylon is less lubricious than polypropylene and polyethylene, right?
A. Probably.
Q. Okay. Now, in that chart, do you see how going across there's different knot configurations, two equals two, three equals two equals one, four equals one equals one, four equals four and four equals four equals four?
A. Yes.
Q. So, going from left to right, two equals two to four equals four equals four, the two equals two is a simpler knot than the four equals four equals four, right?
A. It's not simple or complex. It depends on what the surgeon wants to do. So, he can put more knots to make sure, and in general, they do. They will not stop at two by two. They will probably go to four by four by four to make sure it is there, especially ophthalmic use.
Q. Okay. And if you turn to page ARM 25137 --
A. Thirty-seven, yeah.
Q. Okay, of Cohan, the last paragraph of the first column --
A. Yeah.
Q. -- do you see the sentence beginning

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"Although"? The first column --
A. Did you say first column?
Q. First column, last paragraph.
A. Last paragraph.
Q. The sentence beginning, "Although."
A. "Although," yes.
Q. Cohan states, "Although laboratory testing showed that the polyethylene fiber has a somewhat lower knot holding strength with simpler knots than the other three polymers, more complex knots than are commonly used would realize polyethylene's great knot pull strength."
Do you see that?
A. Yes.
Q. Okay. So, Cohan was calling the more -- the additional knot configurations more complex, right?
A. That's what -- if he meant by that.
Q. Well, did you understand that's what he means when you read this reference?
A. Well, I -- I think that normally for a surgeon, they will put as many knots they can to make sure it's secure, and it's nothing complex or simple about it.
Q. Well, if you look at the author, the author

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1 in the monomer?
2 A. Yeah -- well, it's not a monomer, in the
3 polymer.
4 Q. In the polymer?
5 A. Yeah.
6 Q. I'm confused. Are you saying that the
7 monomer unit in all types of polyethylene is the
8 same or different?
9 A. Mostly same, yeah.
10 Q. Mostly same, okay.
11 Would one of ordinary skill in the art
12 between 1988 and 1992 think that the term
13 "polyethylene" refers to low-density polyethylene
14 or includes -- should I say includes low-density
15 polyethylene?
16 A. Yeah, it would.
17 Q. It would? But not ultra high? Is that
18 your opinion?
19 A. Ah, they will also include ultra high,
20 because there are different properties, so they
21 will include also ultra high, as well as
22 low-density.
23 Q. Okay. I'd like to turn to polypropylene as
24 used in the '446 patent, Exhibit 3 to your first
25 report. Do you see the '446 patent?

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1 A. Yeah.
2 Q. Exhibit 3?
3 A. Exhibit 3.
4 Q. Right.
5 A. Yeah, I'm at this.
6 Q. No, Exhibit 3. I'm sorry, that's Exhibit
7 3. I'm sorry. Yeah, if you would go to column 4,
8 please.
9 A. Yeah.
10 Q. Okay. Beginning at line 9 through 32, do
11 you see that?
12 A. Nine through 32, yeah.
13 Q. Okay. That paragraph says, "Preferably,
14 the continuous filaments which make up the first
15 and second set of yarns are derived from
16 nonabsorbable polymers."
17 Do you see that?
18 A. Yes.
19 Q. Is ultra high molecular weight polyethylene
20 a nonabsorbable polymer?
21 A. Yes.
22 Q. Okay. Then it says, "In a preferred
23 embodiment, the first set of yarns acts as
24 lubricating yarns to improve the pliability, or
25 compliance, and surface lubricity of the

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1 heterogenous braid."
2 Do you see that?
3 A. That is correct.
4 Q. Ultra high molecular weight is a
5 lubricating yarn, right?
6 A. Yes.
7 Q. Okay. Then it says -- further down it
8 says, "Such fiber forming polymers include
9 perfluorinated polymers," and describes some of
10 those, and then it says, "as well as
11 non-perfluorinated polymers," and refers to
12 polyethylene and PE, right?
13 A. Right.
14 Q. Okay. Ultra high molecular weight
15 polyethylene came as fibers before 1992, right?
16 A. Yes.
17 Q. Okay. Now, do you see where in the end it
18 says, "The preferred polymers for the first set
19 are PTFE, PETFE, FEP, PE and PP"?
20 Do you see that?
21 A. Yes.
22 Q. Okay. That's column 4, lines 28 to 31.
23 Did you understand that sentence to refer
24 to all types of polypropylene or just certain
25 types of polypropylene?

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1 MR. TAMBURO: Objection, vague.
2 THE WITNESS: This is general purpose
3 polyethylene, which it provides the lubricity and
4 as well as pliability and compliance, not ultra
5 high molecular weight polyethylene.
6 BY MR. BONELLA:
7 Q. Okay, that wasn't my question. Listen to
8 the question.
9 Did you understand that sentence to refer
10 to all types of polypropylene?
11 MR. TAMBURO: Objection, vague.
12 THE WITNESS: The fiber-forming
13 polypropylene, yes.
14 BY MR. BONELLA:
15 Q. All types, okay.
16 Did you understand -- do you see where it
17 refers to PVDF?
18 A. Yes.
19 Q. Did you understand this paragraph to be
20 referring to all types of polyvinylidene fluoride?
21 A. Yes.
22 Q. Okay. Do you see where it refers to PTFE
23 in that paragraph?
24 A. Yes.
25 Q. Did you understand it to be referring to

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,
Plaintiff,
v.
ARTHREX, INC., a Delaware Corporation
Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE
- VOLUME TWO -
Washington, DC
Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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Q But for known suture materials, the sterilization parameters for ethylene oxide are well-known to one of ordinary skill in the art?
A For the suture that are currently used. But new suture like the ones described '446, there isn't, at least my opinion. One has to run the test to find out if there is or there isn't.
Q Well, sterilization of -- of PET was known, right, in 1988, of PET for fibers for sutures was well-known with ethylene oxide, right?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q Okay. And sterilization procedures for PTFE were -- with sterile -- with ethylene oxide were well-known in 1988, right?
MR. TAMBURO: Objection, vague.
A It's also known, yes, but it -- it is also known that PTFE properties are affected by gamma radiation.
BY MR. BONELLA:
Q But ethylene oxide was known in 1988 that they are --
A Yes.
Q -- generally substantially not affected?

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A Yes.
MR. TAMBURO: Objection, vague.
BY MR. BONELLA:
Q I'd like to turn to your rebuttal report, which is Exhibit 356. Page 18, you talk about the Harpell patents.
A Yes.
Q Did you consider in your analysis whether the Harpell patents disclose a coated suture?
MR. TAMBURO: Take your time to read the report if you need to.
A To best of my recollection, it didn't.
BY MR. BONELLA:
Q Okay. Well, if the Harpell patents did describe coated sutures, would that change your opinion?
A Yeah.
Q Why?
A Because was refer -- I mean, the coating is an issue, whether coating does or does not change properties of this material.
MR. BONELLA: Okay. I'd like to ask you about some other issues. Let's take a quick break. I need to organize myself.
THE VIDEOGRAPHER: You're now going off the video record at 12:01 p.m.
(A recess was taken from 12:02 p.m. through 12:14 p.m.)
THE VIDEOGRAPHER: We're now back on the video record. The time is 12:14 p.m.
BY MR. BONELLA:
Q Dr. Mukherjee, did the three reports that you provided in this case contain all the opinions that you have in this case?
A At this moment, yes.
Q Okay. Have you been asked to develop any other opinions?
A No.
Q Okay. Are you an expert in the area of suture design?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q And what -- what's your basis for saying that?
A I work in suture industry more than 13 years.
Q Okay. And when -- you stopped working in the suture industry in the '80s?
A '87.

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Q Okay. And are you still expert in the area of suture design today?
MR. TAMBURO: Objection, vague.
A Yes.
BY MR. BONELLA:
Q Even though you haven't worked in the industry?
A But I have worked on projects involving sutures in LSU.
Q Okay. Going back to sterilization for a minute, the Cohen reference, remember Cohen?
A Yes.
Q Does Cohen describe how to sterilize the suture that he made?
A Yes, he did.
Q In the -- in the document? So would -- so would --
MR. TAMBURO: If you need to review it, review it.
BY MR. BONELLA:
Q So is that a sterilization for an -- the ultra high molecular weight polyethylene monofilament suture that he described?
A That was one of -- let me look at that.
Q Excuse me?

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MR. TAMBURO: Objection, vague.
A Enough information for a scanning microscopy is not very conclusive. They may or may not be.
BY MR. BONELLA:
Q You don't know?
A I don't know.
Q Okay. Does the coating on FiberWire prevent the PET yarns and the PTFE yarns from each providing their individual properties to FiberWire?
MR. TAMBURO: Objection, vague.
THE WITNESS: Now please correct me.
MR. TAMBURO: And -- and -- and -- and --
THE WITNESS: FiberWire does not contain a PTFE.
BY MR. BONELLA:
Q Oh, I'm sorry. Did I misspeak?
A You just said that.
Q I'm sorry.
Does the coating on FiberWire prevent the PET fibers, PET or ultra high molecular weight polyethylene fibers from providing contribution to FiberWire's properties?
MR. TAMBURO: Objection, vague.
A No.

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BY MR. BONELLA:
Q Okay. I'd like to go to your first report, invalidity, Exhibit 239. If we go to tab -- tab 9 --
A Tab 9.
Q There's an excerpt from Dr. Steckel's report.
A Right.
Q It's only a -- a one-page excerpt from his laboratory notebook.
A Yes.
Q Okay. Did you select that one page to put in your report out of his entire notebook, or were you given that one page?
A No, I have the entire notebook.
Q Okay. Why'd you pick -- did you consider the remainder of his notebook when -- when you select that individual page to attach to your report?
MR. TAMBURO: Objection. Well, not an objection, but if you need -- to the extent you need to read the context of why you cited this, please do so.
A Because it is very clear that he was talking about difficulties in core popping and braid looseness.

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BY MR. BONELLA:
Q Okay. Do you know what samples on that page he was talking about, when -- when they were made?
A Well, according to the lab, his notebook page signed was date of '89 -- I mean '89.
Q Right.
A That's what it says here.
Q Okay. Do you know when those samples were made that are discussed on that page?
A It's February 2, 1989 at the top. That's when the lab entry is.
Q Okay.
A I assume that's when the samples were made.
Q Okay. I'd like you to turn to Exhibit 26 to Exhibit 359, the report of Dr. Matthew Hermes, which contains a larger excerpt of Dr. Steckel's report right here. And if I could draw your attention to page DMI002617, okay?
A Right here.
Q Right here. 17. Okay --
A 1617.
Q Here's an entry on DMI002617 is June 6, 1988?

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A That's correct.
Q Okay. And if you look at the next page, shows a chart of samples, composite braid evaluation, braid constructions. Do you see that?
A Yes.
Q Did you consider that, those constructions?
MR. TAMBURO: Take your time, Dr. Mukherjee.
A I believe I did.
BY MR. BONELLA:
Q Okay. CBE15, do you see CBE15 sample?
A Yeah.
Q Do you know what the construction of that sample was?
MR. TAMBURO: Objection, vague.
A Was PTFE, 11049 in the denier and the fiber. This column on these other things are not there.
BY MR. BONELLA:
Q Do you know what the construction of CB15 was?
MR. TAMBURO: Objection, vague.
A If I understood, you are asking the --
BY MR. BONELLA:

EXHIBIT 7

PCT

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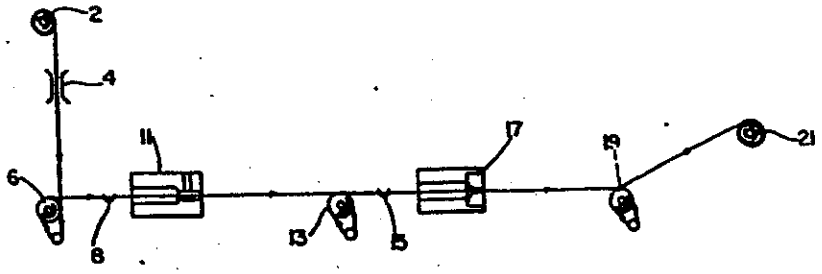

(57) Abstract

A composite surgical suture of extraordinary high knot strength and capable of use over a range of United States Pharmacopeia (USP) suture sizes is prepared by coating or covering a core of a fiber-forming synthetic polymer material having a knot tenacity of at least 7 grams per denier with a conventional suture material. Illustrative of suitable core materials are 'Kevlar' and high strength fully chain-extended crystalline polyethylene.

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COMPOSITE SURGICAL SUTURES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to improved surgical sutures having extremely high knot strength and to methods for their preparation. More particularly, the invention is directed to composite surgical sutures having a knot strength that enables them to be used over a range of suture sizes classified by the United States Pharmacopeia (USP).

Brief Description of the Prior Art

Surgical sutures are generally divided into two broad classes: (1) absorbable sutures, either natural or synthetic, which are absorbed by the body and (2) non-absorbable sutures, which remain in the body for prolonged periods of time or are removed when the wound heals.

From the patient's viewpoint, whether an absorbable or non-absorbable suture is employed, assuming no toxicity of the suture implant, it is a surgical dictum that the finest suture should be used and that the knot should have the least mass. This dictum is based upon the belief that problems in suture implants are directly related to the size of the suture and the bulk of the mass, i.e., the larger the bulk, the greater the probability of trouble in healing.

Undoubtedly, this was the rational for the original establisnment of the USP classification which divides non-absorbable sutures into seventeen sizes: 10/0, 9/0, 8/0, 7/0, 6/0, 5/0, 4/0, 3/0, 2/0, 0, 1, 2, 3, 4, 5, 6, 7. A few additional

sizes are used which are not USP. Considering that silk was the most widely used non-absorbable suture in the mid-twenties and thirties, this size differentiation was based upon manufacturing. These seventeen sizes could be differentiated one from another by eye. If a finer differentiation were desired, it would not be accomplished becasue of the variation in the raw material as extruded by the silk worm. This classification has been quite useful. Obviously, the number of sizes cannot be considered "standardization" by any means. The sizes are numerous. Unfortunately, it has not been possible to coalesce size because the finer sizes do not have the adequate knot break strength to substitute for the next size.

A further long term problem in surgery is post-operative hernia. It is a truism that scar tissue never achieves the tensile strength of normal tissue. Hernias have occurred many years post-operably through the scar. If a suture were developed which would leave as a residue a non-absorbable suture to support that scar tissue, it would undoubtedly decrease and most likely eliminate the post-operative hernia as a complication.

Composite sutures having a reinforcing core are known in the prior art. None, however, achieve the aforementioned characteristics desired in a suture.

Accordingly, it is an object of the invention to provide a surgical suture with knot strengths so great that suture of much less foreign material is left in the body.

Another object of the invention is to provide a surgical suture having a knot strength that renders it useful over a range of surgical sizes within the USP classification of graded suture sizes, and thus

having the ability to replace the USP graded scale of sizes with just a few finer sutures whose strength would cover the entire range.

A further object of the invention is to provide a composite suture which leaves a residue of non-absorbable suture to support scar tissue and, therefore, decreases or eliminates post-operative hernia as a complication.

Another object of the invention is to provide a method of preparing surgical sutures having extremely high knot strength whose surface characteristics can be tailored to meet desired properties.

A further object of the invention is to provide composite sutures capable of using needles which more closely approximate the outer diameter of the suture.

A further object of the invention is to provide a composite suture having lateral strength, that is, a suture stabilized against abrasion, kinking and/or fibrillation during knotting.

SUMMARY OF THE INVENTION

These and other objects of the invention are obtained by a sterile, surgical suture having an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier coated with a film and fiber-forming surgical material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

The elongated core of the sutures of the invention can be formed of any fiber-forming synthetic polymer, such as a polyamide, polyolefin, polyester

and the like, having a straight pull tenacity of at least 15 grams/denier, preferably up to 70 or more grams/denier and a knot tenacity of at least 7 grams/denier, preferably up to 30 or more grams/denier. By "knot tenacity" as used herein and in the appended claims is meant knot break strength divided by the denier. Unless the synthetic polymer making up the suture core of the invention meets the aforementioned knot tenacity properties, the resulting coated core fails to provide a suture which achieves the desired objects of the invention.

Illustrative of synthetic polymer materials suitable for use as the core of the suture of the invention are fiber-forming aromatic polyamides in which the chain extending bonds from each aromatic nucleus are essentially coaxial or parallel and oppositely directed. The term "aromatic nucleus" is used herein to include individual enchained aromatic rings and fused-ring aromatic divalent radicals. The preferred polymers include carbocyclic aromatic polyamides containing up to 2 aromatic rings, including enchained non-fused rings (e.g. 4, 4'-biphenylene) or fused rings (e.g. 1, 5-naphthalene) per amide linkage. The chain-extending bonds from these aromatic rings are para-oriented and/or essentially coaxial or parallel and oppositely directed.

Highly preferred polyamides are characterized by recurring units of the formula:

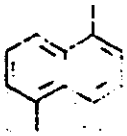
(I)

wherein R and R' (when the chain extending bonds are essentially coaxial) are selected from the group of:

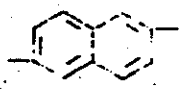
1,4-phenylene, and

4,4'-biphenylene

and R and R' (when the chain extending bonds are essentially parallel) are selected from the group of:



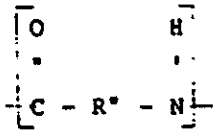
1,5-naphthylene, and



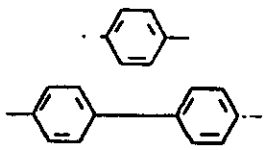
2, 6-naphthylene

R and R' may be the same or different and may contain substituents on the aromatic nuclei.

Additional highly preferred polyamides of this invention are characterized by recurring units of the formula:

(II) 

wherein R" is selected from the group of:



Similarly R" may contain substituents on the aromatic nuclei.

As previously stated, the aromatic nuclei of the polymers of this invention may bear substituents. These substituents should be non-reactive during the polymerization and preferably also should be non-reactive (e.g. thermally) during subsequent processing of the polymer, e.g., heat treating of a shaped fiber thereof. Such reactivity is undesirable in that it may cause cross-

linking of the polymer and may adversely effect the dope and/or fiber properties. Among the preferred non-reactive substituents may be names halogens (e.g., methoxy and ethoxy), cyano, acetyl, and nitro. Other suitable substituents non-reactive during the polymerization will be evident to those skilled in the art and are contemplated herein provided such do not adversely affect the desired properties of the dopes and/or fibers of this invention, e.g., due to factors such as steric hindrance. Generally, it is preferred that no more than two (and more preferably no more than one) suitable substituents be present per aromatic nucleus. However, more than two such substituents may suitably be present if the substituent is a relatively small group e.g., methyl.

Both homo-and co-polyamides having substituted or unsubstituted aromatic nuclei, as described above, are well suited for the dopes and fibers of this invention. Random copolymers are preferred copolymers. By the term "random" is meant that the copolymer consists of molecules containing large numbers of units comprised of two or more different types in irregular sequence. The units may be of AB (e.g., from p-aminobenzoyl chloride hydrochloride), AA (e.g., from p-phenylenediamine or 2,6-dichloro-p-phenylene diamine), or BB (e.g., from terephthaloyl or 4,4'-bibenzoyl chloride) type or mixtures of these, provided always that the requirements of stoichiometry for high polymer formation are met. It is not necessary that the relative numbers of the different types of the unit be the same in different molecules or even in different portions of a single molecule.

One or more of these polymers may suitably be

used in the fibers of this invention, i.e., a single homopolymer; a single copolymer; or homopolymer and/or copolymer blends are suitable herein.

While the polymer chains described above consist essentially of amide links (- CONH -) and aromatic ring nuclei as described above, the polymers useful for preparing the core of this invention may also comprise up to about 10 percent (mole basis) of units not conforming to the above-cited description, e.g., aromatic polyamide-forming units whose chain extending bonds are other than coaxial or parallel and oppositely directed, e.g., they may be metaoriented, or of linkages other than amide, e.g., urea or ester groups.

Among the suitable aromatic polyamides may be named poly(p-benzamide); poly(p-phenylene terephthalamide); poly(2-chloro-p-phenylene terephthalamide); poly(2,6-dichloro-p-phenylene 2,6-naphthalamide); poly(p-phenylene p;p'-biphenyldicarboxamide); poly(p,p'-phenylene benzamide); poly(1,5-naphthylene terephthalamide); ordered aromatic copolyamides such as e.g., copoly(p,p'-diaminobenzanilide terephthalamide), and random copolyamides such as, e.g., copoly(p-benzamide/m-benzamide) (95/5); and many others.

These aromatic polyamides generally have an inherent viscosity and preferably greater than 1.0. Inherent viscosity (ηinh) defined by the following equation:

$$\eta inh = [\ln (\eta rel)/C]$$

wherein (ηrel) represents the relative viscosity and C represents a concentration of 0.5 gram of the polymer in 100 ml of solvent. Exemplary of such aromatic polyamides are those known as the "Kevlar"

series, products of the DuPont corporation, which generally have a straight pull tenacity of about 18 to 25 grams per denier and a knot tenacity of at least about 7 grams per denier. Further examples of such aromatic polyamides and their methods of preparation can be found, for instance, in U.S. Patent Nos. 3,063,966, 3,600,350, 3,671,542 and 3,919,587 all incorporated herein by reference.

Another example of a synthetic polymer suitable for use as the core of the suture of the invention are high strength polyolefins such as polyethylene which provides fibers having a straight pull tenacity of about 25-50 grams/denier and a knot tenacity of about 7 to 17 grams/denier. These polyolefin fibers are characterized by full chain extension and high crystallization and can be prepared: (1) by ultradrawing of the solidified crystalline polyolefin material that is, by further development of the traditional cold drawing process, and (2) by extending the chains in random state (melt or solution) and inducing them to crystallize in the extended form subsequently. Polyolefins having these characteristics and their method of preparation are described in Keller, A. and Barham, P.J. "High Modulus Fibres", Plastics and Rubber International, February, Volume 6, No. 1 (1981), herein incorporated by reference.

The core of the surgical suture of the invention can be either a monofilament or of multifilament construction. The latter is ordinarily preferred since the coating of suture material subsequently applied generally exhibits stronger adhesion to multifilament cores. The liquified suture material coating tends to penetrate and fill the interstices of a multifilament core as well as

coating the core, thereby anchoring the coating thereto. Multifilament cores can take the form of braids, twisted polyfilaments, yarns and the like.* It should be noted that while the synthetic polymer materials contemplated for use as the core of the composite sutures of the invention, have high axial strength, they are not ordinarily suitable for use as sutures since they do not possess the necessary lateral strengtn and, therefore, tend to abrade, kink and/or fibrillate during knotting. Coating of the core with a suture material pursuant to the present invention has been found to unexpectedly stabilize, i.e. provide lateral strength resistance against such action thereby rendering suitable for use as sutures these synthetic polymer fibers normally unsuitable for such use.

The surgical suture material used to coat the core can be any film-forming material commonly used in the construction of absorbable and non-absorbable sutures. In general these suture materials when drawn into fibers exhibit straight tensile strengths of about 4 to 10 grams/denier. Examples of the non-absorbable type suture materials are silk (fibroin), polyolefins, such as polyethylene and polypropylene, polyesters such as polyethylene terephthalate and nylon. Examples of absorbable type materials useful as the coating for

* The suture material in the form of multi or monofilament yarn may also be present initially as a core around which the high strength yarn which eventually becomes the core in the finished suture is braided or twisted or it may be formed into a plied, twisted, braided or co-mingled construction with the high strength yarn.

the core include collagen and the synthetic absorbable materials such as polylactide, polyglycolide and copolymers of lactide and glycolide with each other and with other reactive monomers such as those described, for instance, in U.S. Patent Nos. 3,636,952 and 2,683,136, which patents are herewith incorporated by reference. Such synthetic absorbable polymers are sometimes referred to herein as simply homopolymers and copolymers of lactide and glycolide.

The amount of suture material coated onto the core will vary depending upon the constructon of the core, whether monofilament or multifilament, the number and tightness of braid or twist, the particular tensile strength and knot tenacity of the core, the particular suture material used as the coating and its nature, e.g. melt, solution or solid. In general, when the coating is a non-absorbable suture material, the coating will constitute about 5 to about 10% by weight of the coated core. On the other hand, when the coating is an absorbable suture material, the coating may constitute about 5 to 90% by weight of the coated core.

The coatings can be applied by a variety of suitable techniques well known in the coating art. For example, the coatings can be applied to the core by solution coating, melt coating, extrusion coating and the like.

In melt coating, for example, the uncoated core under tension is slowly passed through a melt of the suture material and then through a die having an orifice smaller than the upper diameter specification for the suture size desired, heated above the melting point of the coating materials, to trim

off excess coating material and shape the composite. Multiple coatings may be applied if necessary.

In solution coating, the suture material is dissolved in a suitable solvent and the core is slowly passed through the coating solution thus formed. The treated core is then passed continuously through a tubular oven heated to an elevated temperature to evaporate the solvent and coalesce and solidify the suture material that remains.

A preferred coating technique when the core being coated is of multifilament construction comprises initially either solution coating or melt coating the multifilament core while the latter is held under a suitable tension and allowing the liquified coating material to penetrate or infiltrate the interstices of the core, thereby forming roots which help anchor the coating of the core. A second layer of the same suture material may then be applied to the impregnated core by any of the conventional coating methods.

In a typical extrusion coating process the core is passed through the cross-head die of a conventional wire coating extrusion apparatus. Pellets of the coating material are introduced into the plastification zone of the extruder wherein they are plasticized into a melt which is forced through the annular die of the extruder and onto the core.

Which coating technique is employed will usually depend upon the particular core utilized. Aromatic polyamide cores, for example, lend themselves to melt or extrusion coating because of their high melting points. The high strength polyethylene cores, on the other hand, have

relatively low melting points, e.g. about 145°C, and must be treated differently. With them, solution coating of the monoor multi-filament cores is the chief method.

According to a preferred embodiment of the invention, when the core being coated is an aromatic polyamide, it is subjected to both a precoating stage and finish coating stage, each of which will oe discussed below in more detail.

Impregnation/Precoating Stage

The impregnation/precoating operation of the invention can be conducted using a thread composed of a core made up of multifilaments of a suture material and a plurality of fibers of a synthetic polymer having a tenacity of at least 18 grams/-denier and knot tenacity of at least 7 grams/-denier. The thread can be formed in the usual manner as by twisting, braiding, etc., a plurality of the synthetic polymer fibers around the suture material core. The thread, that is, the covered core is then heated to temperatures above the melting point of the multifilament core material passing it through any suitable oven during which passage the suture material melts and under the tension developed and/or applied exudes upward through the polyfilamentous synthetic polymer component and onto its surface. The amount of coating employed should be sufficient to not only fill all the interstices of the multifilament core component during the melting period but to also coat the surface of the yarn or thread component. Any excess coating material which may have melted out is trimmed off. While the heating of the covered core mixed yarns can be effected with or

without stretching of the thread in some instances, a better final suture is obtained when the yarn is maintained under tension with little or no stretch applied at this stage. It is at this stage that the basic solid coated core structure is developed.

The impregnated and coated core is then passed through a heated dye which trims coating nubs from the core and otherwise smooths the external surface of the thread. Stretch may also be applied during the smoothing operation, but again, best results are obtained with no or minimum stretch. The thread may be passed through the heating oven or smoothing die as many times as is necessary to obtain a smooth, nub-free surface. Advantageously, in smoothing down the nubs not only should excess surface coating be removed, but some of it should be used to fill the ups and down of the thread's surface in order to obtain a sufficiently smooth undercoat structure. If this is not done, the coating remaining on the surface follows the contours of the thread and any subsequently applied coating will follow these contours.

The temperatures employed in the heating oven will vary depending on the coating employed, the proportions of coating material to core, the speed at which the core is passed through the oven and whether the heating and/or smoothing is conducted under stretch conditions. As aforementioned, the temperature should be raised above the melting point to a level at which the coating material exudes through the thread as a gelatinous mass which can then be seen on the surface of the thread when it cools. Excessively high temperatures which thin the coating material to a point where it runs off should be avoided as they tend to exude too

much coating material and fail to produce a solid case structure.

Generally speaking, when the impregnation/precoating operation is conducted under stretch conditions, distribution of the coating material throughout the thread and exudation to the surface occurs at lower temperatures than when no stretch is applied. It is important to note, however, that giving the core a high level of stretch in the impregnation/precoating operation reduces or eliminates the ability to apply stretch in the subsequent finish coating stage, in accordance with the preferred embodiment of the invention described below, where it may be used to adjust finished suture properties such as break elongation by additional heat treatment of the highly stretched precoated thread.

The optimum melting temperatures employed in the impregnation/precoating operation will depend primarily upon which suture coating material is employed. The smoothing die temperature will also be above the melting point of the coating material and below the melting point of the core. Usually it will conform closely to the temperature employed in the impregnation/precoating stage preferably about 5 to 15 degrees below that used in the impregnation/precoating stage.

Finish Coating Stage

In the preferred embodiment of the invention, the final stage in obtaining the composite suture structure is to melt extrude coating material onto the smoothed impregnated/precoated thread. Any of the conventional extrusion apparatuses can be employed for this purpose. The smooth precoated

thread is simply fed through the extrusion coating die and coated with additional coating material of the same type as used in the impregnation/ precoating stage. As aforementioned, it is important to note that the smooth impregnated/ precoated thread subjected to the coating stage be essentially free of an undulating surface. The extrusion temperatures employed in the impregnation/ precoating stage although it has been found that the higher the extrusion coating temperature, other conditions being equal, the greater the finished suture diameter. This is due to decreased melt viscosity with increased temperature which results in increased polymer flow under a given applied force.

The following examples are included to further illustrate the novel composite sutures of the invention and their preparation. In the examples, reference is made to the following drawings wherein: Fig. 1 is a schematic drawing of an apparatus useful in the impregnation/precoating stage of the present invention; Fig. 2 is a schematic drawing of an apparatus useful in the extrusion coating of the suture impregnated and precoated by use of the apparatus of Fig. 1; and Fig. 3 is a cross-section of the extrusion die in Fig. 2 on a larger scale.

Example I

Directing attention to the drawings, using a conventional New England Butt braider machine 4 strands of "Kevlar", a tradenamed material of DuPont DeNemours, of 30-50 denier having a straight pull tenacity of approximately 7.5 grams per denier are braided around a single core of continuous 40 denier polypropylene having a straight pull tenac-

ity of approximately 4 grams/denier. The raw braid thus formed is wound around a reel 2, and fed through a tensioner 4, about a feed roll (Godet) 6, guide 8 and into a heated 10 cm long tubular oven. The lumen of an extrusion coating die without feed serve this purpose and is designated Heated Zone I in Fig. 1. A draw roll (Godet) 13 pulls the raw braid through the oven without stretch, that is, at a stretch ratio (SR) of 1:1. The Heated Zone I is maintained at a temperature of 230°C. Under these conditions all the polypropylene melts and is entirely distributed throughout the braid interstices and onto the surface of the braid. No solid polypropylene core residue remains.

As the braid emerges from Heated Zone I, large quantities of excess polypropylene which have melted out are trimmed off manually. The braid then continues through a Guide 15 to Heated Zone II which contains a smoothing die 17 having a 0.2 mm diameter that trims and smooths down nubs that are formed on the braid. Heated Zone II is maintained at a temperature of about 220°C for the smoothing operation. The smoothed braid is pulled through Heated Zone II by a draw roll (Godet) 19 and onto receiving reel 21. The speed at which the braid passes through both Heated Zone I and II is approximately 1-1.8 M/min. The precoated braid is passed through the smoothing die 17 three times so as to obtain an impregnated/precoated braid of the desired smoothness.

Referring to Fig. 2, reel 31 of smooth impregnated/precoated braid prepared as above is passed through a tensioner 33, to feed roll (Godet) 35 which feeds the braid through guide 37 into extrusion coating die apparatus indicated generally

as 39. Polypropylene chips are melted in heated reservoir 41 maintained at a temperature of 260°C and the melt is forced by means of extruding weights 43 applied at a force of 0.233 kg to a piston 45 into and through the extrusion coating die.

Directing particular attention to Fig. 3, the extruding coating apparatus is comprised of a holder indicated generally as 47 which houses a hollow lumen member 49 a spinneret 57 having an outlet 52. The lumen member 49 essentially positioned within the holder 47 so as to provide an annular chamber 53. A gasket 55 seals one end of the member 49 within the holder while the other end is supported by slotted plate 60. The lumen member contains an inlet 59 and an outlet 61. Between outlet 61 and outlet 52 of the spinneret 57 is positioned a hollow needle 63. The impregnated/precoated thread 65 passes consecutively through lumen member 49, hollow needle 59, outlet 52 and is coated with melt as it emerged from the die. The coating die is maintained at a coating temperature of 235°C.

The coated filament is then taken up on draw roll 48 which applies stretch. Tension is let down on draw roll 50 which is run more slowly than draw roll 48. The yarn velocity is 1.43 M/min. and the total stretch ratio (SR) is 1.02. The finished suture is finally wound around receiving reel 51.

The result is a finished composite suture with a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional area and exhibiting a knot break strength of about 3.2 pounds. A knot break strength of 3.2 pounds is equivalent to USP limits of size 2.0 monofilament suture. Thus,

the composite suture prepared can be used as a 5/0, 4/0, or 3/0 suture.

Example II

The process of Example I is repeated substituting a polyethylene terephthalate core for polypropylene core and extrusion coating in extrusion coating die apparatus 39 with polyethylene terephthalate. The result is a composite suture having a 5/0 diameter "Kevlar" core accounting for approximately 90% of the cross-sectional volume coated with polyethylene terephthalate exhibiting a knot break strength of about 3.5 pounds which is a knot brek strength above the USP limits for a 2/0 size suture. Therefore, the composite suture prepared could be used for sizes 5/0, 4/0, 3/0 and 2/0 according to the physician's wishes.

Example III

Fibroin (silk) is dissolved in a aqueous solution of 62% zinc chloride to give a solution having fibroin weight % concentrations in the range of 5-20%. The resulting solution is maintained at approximately its boiling point and "Kevlar" yarn of Example I is pulled through the solution at a constant rate as to fully impregnate and coat the yarn. The impregnated and coated yarn is then dried by passing it through a tubular oven maintained at heating temperatures up to 130°C. The heat treatment evaporates the solvent and helps to form a continuous fibroin film. The composite suture is then washed with cold water to remove residual zinc chloride.

The resulting composite suture with a size 5/0 "Kevlar" core containing approximately 5% by weight fibroin exhibits a knot break strength of approximately 3.5 pounds which is equivalent to a silk

suture of size 2.0. In other words, the silk-coated "Kevlar" composite suture could be used instead of silk in the following sizes: 5/0, 4/0, 3/0 and 2/0.

Example IV

A size 5/0 high strength fully chain-extended polyethylene multifilament yarn having a straight pull tenacity of 50 grams/denier and a knot tenacity of 15 grams/denier is pulled through a 10% solution of polyethylene terephthalate in a solvent mixture of methylene chloride containing 31% by weight hexafluoroisopropanol and then passed through a die to trim off excess solution. The coated core is dried in air and the process repeated to build up the coating to a final composite suture containing 10% by weight polyethylene terephthalate. The composite is washed with water and dried again. The resulting composite suture could be used for sizes 5/0, 4/0, 3/0, 2/0 and 1/0.

Example V

Example I is repeated substituting a polyglycolic acid (PGA) core for the polypropylene core and PGA resin for the polypropylene chips. The resulting "Kevlar"/polyglycolic acid composite has a minimum knot break strength in the range of 1550-1700 grams. Since commercial non-absorbable "Prolene" sutures of size 3/0 has a knot strength of 1550-1650 grams, this means that a size 3/0 "Kevlar"/polyglycolic acid suture will retain the knot break strength of 3/0 "Prolene" after absorption of all the polyglycolic acid. Thus, the "Kevlar"/polyglycolic acid suture prepared could be used for sized 3/0, 4/0 and 5/0.

When 6/0 size "Kevlar" reinforcing core is used with a non-reinforcing PGA coating, the core by

itself will give a knot strength midway between size 4/0 and 5/0 based on "Prolene" knot strength but above the USP standards for 4/0. Thus, PGA coated "Kevlar" composites with a 6/0 core could be used for size 6/0, 5/0 and possible size 4/0.

With size 7/0 reinforcing core and PGA non-supportive coating 6/0 strength is obtained. Thus, PGA coated, 7/0 core "Kevlar" can be used for sizes 6/0 and 7/0.

Using high strength, extended chain polyethylene having 50 gram/denier straight breaking tenacity, with approximately 1/3 of this converting to knot tenacity, a 5/0 size reinforcing high strength polyethylene core of about 0.140 mm in diameter will impart at least the knot strength of a 2/0 suture to the composite. Thus, a PGA-coated high strength polyethylene 5/0 core can be used to make sizes 2/0, 3/0, 4/0 and 5/0 absorbable, non-absorbable composite sutures.

With high strength polyethylene 6/0 size reinforcing core of about 0.90 mm diameter and a non-supporting PGA coating, the core itself will provide enough knot strength for sizes 4/0, 5/0 and 6/0 based on the knot strength of "Prolene".

With high strength polyethylene 7/0 size reinforcing core of about .060 - .065 mm in diameter and non-reinforcing PGA coating, the core itself will give knot strength sufficient for 5/0, 6/0 and 7/0 composites based on the knot strengths of "Prolene".

With higher strength materials or by increasing the knot strength of the materials mentioned here, a wider spectrum of sizes could be covered with the same fine sized reinforcing core.

In commercial production, needles may be

attached to one end of the composite sutures of the invention and the sutures may be packed in sterile containers. Inasmuch as the sutures are stable for long periods of time witnout a conditioning fluid, the sutures may be dry packed in glass tubes or plastic envelopes. Conditioning fluid may be used to assure maintenance of sterility or as a rust preventing medium for the needle. Eyeless needles are preferred since they cause less tissue damage. Conveniently, the composite sutures of the present invention are formed at convenient lengths, attached to eyeless needle, wound on reels if desired, and placed in containers such as plastic envelopes. The sutures may then be sterilized with ethylene oxide or other conventional gaseous sterilizing agents in accordance with known practices. Alternatively, the sutures may be sealed in the envelopes and then sterilized by using heat and radiation including x-rays, gamma rays, electrons, neutrons, etc.

Another advantage offered by the composite sutures of the invention is that needles of smaller diameter can be attached thereto. In accordance with this feature of the invention the outside cover or coating of suture material at the end of the composite suture is removed by any suitable means as, for instance, by dissolving the cover using a solvent which solubilizes the cover but not the core. The core at the end of the suture is thereby exposed and onto the core is attached as, for instance, by swagging a needle of smaller outer diamter than would be used with a suture of the same outer diameter. The following example illustrates this feature of applicants' invention:

Example VI

The end of a composite suture prepared according to the general procedure of Example I and having an outer diameter of approximately 0.012 inch is dipped one-eighth inch into boilin xylene until the polypropylene cover softens. The polypropylene cover is then manually scrapped off to expose the 5/0 "Kevlar" core. A 0.014 inch diameter needle is swagged onto the core to provide a suture with a needle having a cross-sectional area reduced approximately two-thirds that of needles required for sutures having a 0.012 inch diameter.

IT IS CLAIMED:

1. A sterile, surgical suture comprising an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams per denier coated with a film and fiber-forming surgical suture material, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

2. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is an aromatic polyamide.

3. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

4. A sterile, surgical suture according to claim 1 wherein the aromatic polyamide is poly(1,4-benzamide).

5. A sterile, surgical suture according to claim 1 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

6. A sterile, surgical suture according to claim 1 wherein the surgical suture material is fibroin.

7. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyester.

8. A sterile, surgical suture according to claim 1 wherein the polyester is polyethylene terephthalate.

9. A sterile, surgical suture according to claim 1 wherein the surgical suture material is polyolefin having a straight pull tenacity of about

21. A sterile, surgical suture according to claim 2 wherein the core is a plurality of fibers of said synthetic polymer in a twisted yarn or braided construction.

22. A sterile, surgical suture according to claim 20 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

23. A sterile, surgical suture according to claim 1 wherein the coating of film-forming suture material comprises 5 to 10% by weight of the suture.

24. A sterile, surgical suture according to claim 13 wherein the coating of film-forming suture material comprises 5 to 90% by weight of the suture.

25. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of a synthetic polymer having a knot tenacity of at least 7 grams/denier, with a fiberand film-forming surgical suture material, said coated core when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

26. A method according to claim 25 wherein said coating is effected by solution coating.

27. A method according to claim 25 wherein said coating is effected by melting coating.

28. A method according to claim 25 wherein the coating comprises heating under tension a thread conprised of a plurality of synthetic polymer fibers having a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers

4 to 10 grams/denier.

10. A sterile, surgical suture according to claim 1 wherein the polyolefin is polyethylene.

11. A sterile, surgical suture according to claim 1 wherein the polyolefin is polypropylene.

12. A sterile, surgical suture according to claim 1 wherein the surgical suture material is collagen.

13. A sterile, surgical suture according to claim 1 wherein the surgical suture material is a film-forming absorbable synthetic polymer.

14. A sterile, surgical suture according to claim 13 wherein the absorbable synthetic polymer is selected from the group consisting of film-forming homopolymers and copolymers of lactide and glycolide.

15. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of glycolide.

16. A sterile, surgical suture according to claim 14 wherein the absorbable synthetic polymer is a homopolymer of lactide.

17. A sterile, surgical suture according to claim 1 wherein the core is in monofilament construction.

18. A sterile, surgical suture according to claim 2 wherein the core is in monofilament construction.

19. A sterile, surgical suture according to claim 18 wherein the aromatic polyamide is poly(p-phenylene terephthalamide).

20. A sterile, surgical suture according to claim 1 wherein the core is a plurality of fibers of said snythetic polymer in a twisted yarn or braided constructon.

of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, then smoothing said coating.

29. A method according to claim 28 wherein said smoothing is effected by passing said heated thread through a heated smoothing die.

30. A method according to claim 28 wherein the surgical suture material is selected from polyolefin and polyester.

31. A method according to claim 25 wherein the coating comprises heating under tension a thread comprised of a plurality of synthetic polymer fibers having a straight pull tensile strength of at least 18 grams/denier and a knot tenacity of at least 7 grams/denier in the form of a cover and at least one fiber of a meltable surgical suture material in the form of a core, at an elevated temperature sufficient to melt and liquify the fiber or fibers of surgical suture material but not the fibers of said cover, permitting the liquified surgical suture material to distribute itself throughout the interstices of the cover and onto the surface thereof so as to form a coating on said cover, which is thereby converted to the core of the finished composite suture, smoothing said coating and melt extruding similar surgical suture material onto said smoothed coating.

32. A method according to claim 31 wherein the surgical suture material is selected from polyolefin and polyester.

33. A method according to claim 25 wherein the coating is effected by solution coating.

34. A method of producing a surgical suture having a knot strength rendering it useful over a range of USP suture grade sizes comprising coating an elongated core of synthetic polymer having a knot tenacity of at least 7 grams/denier and a lateral strength insufficient to prevent abrasion, fibrillation or kinking on knotting with a film and fiber-forming surgical material in an amount sufficient to increase the lateral strength of said core and provide resistance against said abrasion, fibrillation or kinking on knotting, said coated core, when constructed into a surgical suture of a particular USP grade size, having a knot strength exhibited by surgical sutures of said suture material at least two USP grade sizes larger.

35. A sterile, surgical suture according to claim 1 having a needle attached to said core.

36. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is an aromatic polyamide.

37. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(p-Phenylene terephthalamide).

38. A sterile, surgical suture according to claim 35 wherein the aromatic polyamide is poly(1,4-benzamide).

39. A sterile, surgical suture according to claim 35 wherein the synthetic polymer is a fully chain-extended polyethylene having a straight pull tenacity of about 30 to 50 grams/denier.

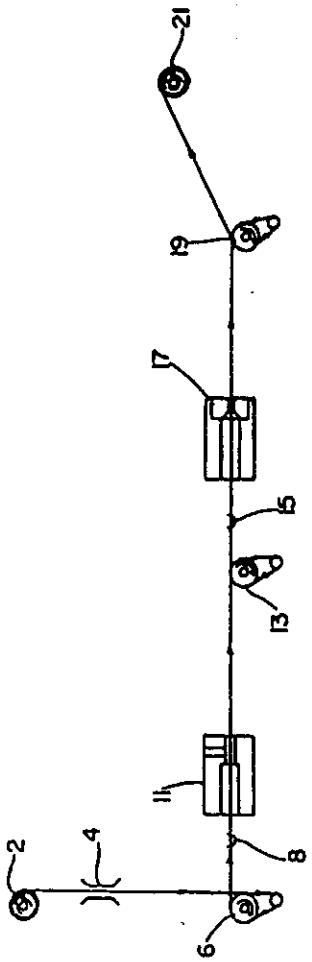


FIG. 1

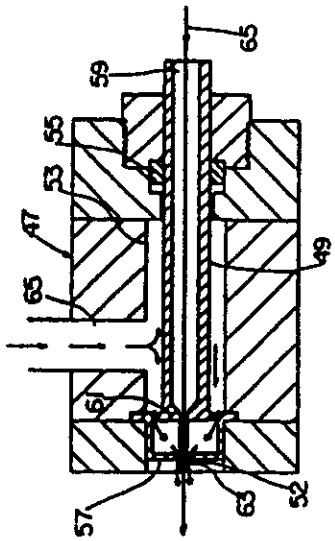


FIG. 3

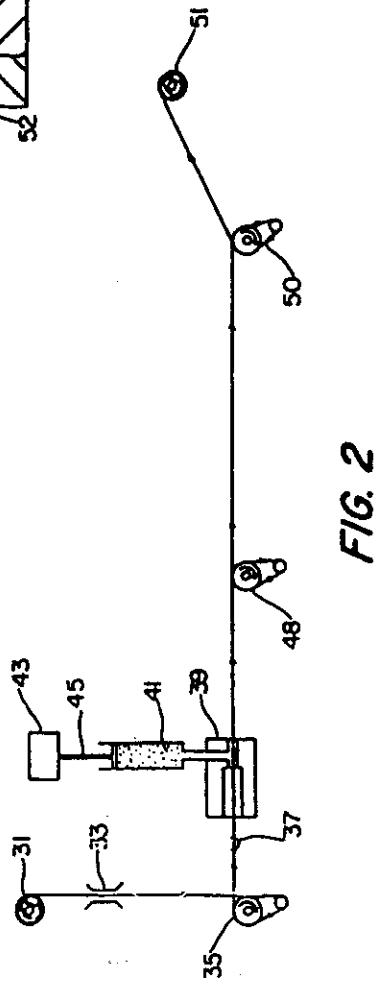


FIG. 2

INTERNATIONAL SEARCH REPORT

International Application No PCT/US84/00918

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int Cl [3] A61L 17/00
US CL 128/335.5

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
US	128/329R, 334R-335.5, Dig. 8, Dig. 18 28/140, 165, 166, 169 66/169R-170, 202 8/Dig. 21 8/490, 529-533, 115.5-115.7, 130.1-132, Dig. 3,

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [4]

cont'd Dig. 9

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]		Relevant to Claim No. [18]
X, Y	US, A, 3,791,388	12 February 1974 HUNTER	1, 6-9, 11-17, 20, 23-35
Y	US, A, 4,014,973	29 March 1977 THOMPSON	23, 24, 31
Y	US, A, 3,359,983	26 December 1967 NORTHEY	5, 10, 23, 24, 39
Y	US, A, 3,630,205	28 December 1971 LISTNER	5, 10, 23, 24, 39
X, Y	US, A, 4,204,542	27 May 1980 BOKROS	23, 24, 35-38
X, Y	US, A, 4,336,357	22 June 1982 BARTOLI	23, 24, 35-38

* Special categories of cited documents: [15]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search [1]	Date of Mailing of this International Search Report [1]
31 JULY 1984	17 AUG 1984
International Searching Authority [1]	**Signature of Authorized Officer [1]**
ISA/US	C. FRED ROSENBAUM

Form PCT/ISA/210 (second sheet) (October 1981)

DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI000180

International Application No PCT/US84/00918

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [10]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers . because they relate to subject matter [12] not required to be searched by this Authority, namely:

2. ☐ Claim numbers . because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [13], specifically:

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [11]

This International Searching Authority found multiple inventions in this international application as follows:

Claims 1-24 and 35-39 are drawn to a surgical suture.

Claims 25-34 are drawn to a method of making a surgical suture.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (supplemental sheet (2)) (October 1981)

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